

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

SYNERON MEDICAL LTD., CANDELA
CORPORATION, AND MASSACHUSETTS
GENERAL HOSPITAL

Plaintiffs,

v.

ENDYMED MEDICAL LTD. AND ENDYMED
MEDICAL INC.

Defendants.

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CIVIL ACTION NO. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital (collectively, “Plaintiffs”) bring this complaint for patent infringement against Defendants EndyMed Medical Ltd. and EndyMed Medical Inc. (collectively, “Defendants”) and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under 35 U.S.C. § 271, *et. seq.*, by Plaintiffs against Defendants for infringement of United States Patent Nos. 9,510,899 (“the ’899 patent”) and 9,095,357 (“the ’357 patent”) (collectively, “Patents-in-Suit”) by making, using, offering to sell, selling and importing radio frequency micro-needle products, such as Defendant’s 3DEEP, PRO, Pure 2.0 and Intensif products.

THE PARTIES

2. Plaintiff Syneron Medical Ltd. is an Israeli company with a number of directly and indirectly owned U.S. subsidiaries, including co-plaintiff Candela Corp, acquired by Syneron in 2011. Syneron's principal place of business is Tavor Building, Industrial Zone, Yokneam Illit, 20692, Israel.

3. Syneron is a leading global aesthetic device company with a comprehensive product portfolio and a global distribution footprint. Its technology enables physicians to provide advanced solutions for a broad range of medical-aesthetic applications including body contouring, hair removal, wrinkle reduction, improving the skin's appearance through the treatment of superficial benign vascular and pigmented lesions, and the treatment of acne, leg veins and cellulite.

4. Syneron is the exclusive licensee of the two asserted patents for clinical applications.

5. Following its acquisition of Candela, a separate aesthetic device company, Syneron is sometimes referred to by the brand name "Syneron Candela." Syneron's United States operations are headquartered in Wayland, Massachusetts. Syneron also has operations in other facilities in the United States, including Irvine, California and San Jose, California, and has invested significant resources into domestic research, design, quality control, testing, and technical support for the products that embody the asserted patents.

6. Plaintiff Candela Corporation is a Delaware corporation. Candela's principal place of business is 530 Boston Post Road, Wayland, MA 01778. Candela is a wholly owned subsidiary of Syneron Medical Ltd. through several intervening corporate entities.

7. Plaintiff MGH is a not-for-profit corporation incorporated in the State of Massachusetts. Its principal place of business is located at 55 Fruit Street, Boston, Massachusetts 02114.

8. The inventions of the patents-in-suit were developed at MGH, who received the patent rights from its employee, inventor Dr. Deiter Manstein. MGH subsequently licensed the patented technology first to Candela, and after Candela's acquisition by Syneron, to Syneron. MGH, as the assignee of the two asserted patents, granted Syneron an exclusive license to the asserted patents in the clinical space, and receives ongoing royalties from Syneron for sales of the patented technology.

9. On information and belief, EndyMed Medical, Ltd. is headquartered in Israel, and located at 7 Bareket St., North Industrial Park, Caesarea, 30889, Israel.

10. On information and belief, EndyMed Medical Ltd. makes direct sales of the accused products in the U.S. through its wholly-owned U.S. subsidiary EndyMed Medical, Inc. Collectively, the two EndyMed entities and their affiliates design, develop, import, and sell after importation aesthetic dermatological devices, including the 3DEEP, PRO, Pure 2.0 and Intensif products, such as the RF micro-needle devices pictured below:



JURISDICTION AND VENUE

11. Plaintiffs bring this action for patent infringement under the patent laws of the United States, 35 U.S.C. § 271 *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Defendants are subject to this Court’s personal jurisdiction pursuant to due process and/or the Massachusetts Long Arm Statute due at least to their substantial presence and business in this State and judicial district, including: (A) at least part of their infringing activities, (B) regularly doing and/or soliciting business in Massachusetts, and (C) engaging in persistent conduct and/or deriving substantial revenue from goods and services provided to customers in Massachusetts. On information and belief, Defendants intentionally offer to sell, sell, and import radio frequency micro-needle products, such as the 3DEEP, PRO, Pure 2.0 and Intensif products in Massachusetts.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1391(c).

THE ASSERTED PATENTS¹

The ’899 Patent

14. United States Patent No. 9,510,899, titled “Method and Apparatus for Dermatological Treatment and Tissue Reshaping” issued on December 6, 2016, to inventor Dieter Manstein. The ’899 patent issued from U.S. Application No. 14/458,644, filed on August 13, 2014. The ’899 patent is a continuation of U.S. Patent Application No. 12,914,201, filed on October 28, 2010, now U.S. Patent No. 9,095,357, which is a division of U.S. Patent Application

¹ No part of this complaint, including any sections herein or exhibit hereto, construes, or is intended to construe, the specification, file history, or claims of any of the asserted patents.

No. 11/098,030, filed on April 1, 2005, now U.S. Patent No. 7,824,394. The '899 patent claims priority to U.S. Provisional Application No. 60/558,476, filed on April 1, 2004. A true and correct copy of the '899 patent is attached hereto as Exhibit 1.

15. MGH owns by assignment the entire right, title, and interest in and to the '899 patent. Syneron is an exclusive licensee of the '899 patent within a specific field of use.

The '357 Patent

16. United States Patent No. 9,095,357, titled "Method and Apparatus for Dermatological Treatment and Tissue Reshaping" issued on August 4, 2015, to inventor Dieter Manstein. The '357 patent issued from U.S. Application No. 12/914,201, filed on October 28, 2010. The '357 patent is a division of U.S. Patent Application No. 11/098,030, filed on April 1, 2005, now U.S. Patent No. 7,824,394. The '357 patent claims priority to U.S. Provisional Application No. 60/558,476, filed on April 1, 2004. A true and correct copy of the '357 patent is attached hereto as Exhibit 2.

17. MGH owns by assignment the entire right, title, and interest in and to the '357 patent. Syneron is an exclusive licensee of the '357 patent within a specified field of use.

FACTUAL BACKGROUND

18. The technology at issue was invented, designed, prototyped, and developed in the United States, through the combined efforts of MGH (in Massachusetts), Candela and Primaeva Medical, Inc. (both in California).

19. The technology was first invented by Dr. Dieter Manstein, an Assistant Professor of Dermatology at MGH and Harvard University. Dr. Manstein, who received an M.D. and a Ph.D. in biomedical physics, is responsible for several ground-breaking developments in dermatology.

20. Dr. Manstein filed the first patent for the technology in 2004, and assigned the patent rights to his employer, MGH. In 2007, MGH originally licensed the exclusive rights to those patents in the clinical setting to Candela, who worked with Primaeva to develop the first working prototype. That same year, the prototype, known as Renasis, was used in clinical trials, demonstrating the effectiveness of the patented technology in treating wrinkles.

21. Starting in 2008, Primaeva worked on implementing the patented technology on a commercial level. The original commercialized product was referred to as Miratone. In 2009, Syneron acquired Primaeva and changed the product name from Miratone to ePrime. In early 2010, Syneron acquired Candela. Upon the latter acquisition, Syneron in 2011 entered into an amendment and restatement of the original MGH-Candela license, to effectively change the licensee from Candela to Syneron.

22. In 2011, ePrime received 510(k) clearance for wrinkle treatment from the U.S. Food and Drug Administration.

23. Ultimately, Syneron changed the name of the commercial patented product from ePrime to Profound, shown below:



24. Syneron's U.S. subsidiary, Candela, in addition to handling marketing and sales for Profound, employs dozens of people in the U.S. to install the patented product, train medical

professionals on use of the patented system, service and repair the patented equipment, and perform research and development to improve the existing product.

25. The patented Profound product (and all the accused infringing products) are aesthetic medical devices that deliver radio frequency (“RF”) energy through micro-needles to small, localized regions of the dermis, beneath the surface of the skin. This, in turn, causes a pattern of thermal damage in isolated regions within the dermis (fractional wounding). When the dermis is fractionally damaged by the energy emitted from the needles, the subsequent healing process results in the formation of new collagen, a volumizing agent that pushes out wrinkles and smooths the skin.

26. The patented Profound system—and Defendants’ accused products—use a handheld applicator with a needle array located on a disposable tip. The handheld applicator is connected to a console containing an RF energy source and a controller, for supplying RF energy to the dermis through the needle tips.

27. The Profound system, the claimed inventions, and Defendants’ accused products control application of RF energy through needles to the dermis to cause fractional wounding and thereby promote improvement in skin aesthetics. Defendants’ patent infringement has and will continue to adversely affect the success of the Profound product line, and has and will continue to adversely affect Syneron, Candela, and MGH.

28. Defendants import and sell the 3DEEP, PRO, Pure 2.0 and Intensif products to dermatologists and clinics throughout the U.S. Defendants advertise the use of the 3DEEP, PRO, Pure 2.0 and Intensif products throughout the U.S. on their website, which includes a physician finder section to search for physicians providing skin treatments using the 3DEEP, PRO, Pure 2.0 and Intensif products in the U.S. On information and belief, at least 13 physicians

in Massachusetts provide skin treatments using Defendants' 3DEEP, PRO, Pure 2.0 and Intensif products.

COUNT I: PATENT INFRINGEMENT OF U.S. PATENT NO. 9,510,899

29. On information and belief, the accused products that are made, used, sold, offered for sale, or imported within the United States after importation by Defendants infringe one or more claims of the '899 patent, either literally or under the doctrine of equivalents.

30. A claim chart that applies independent claims 1, 15, and 20 of the '899 patent to a representative accused product is attached to this Complaint as Exhibit 3.

31. On information and belief, Defendants directly infringe one or more claims of the '899 patent through their manufacture, use, sale, offer for sale, and importation of one or more accused products, in the United States.

32. On information and belief, Defendants knowingly and intentionally induce users of one or more of the accused products to directly infringe one or more claims of the '899 patent by encouraging, instructing, and aiding one or more persons in the United States, including but not limited to end users who test and operate accused products at the direction of Defendants, to make, use (including testing those devices and methods), sell, offer to sell, or import one or more of the accused products in the United States, in a manner that infringes the '899 patent.

Defendants have had knowledge and notice of the '899 patent at least as early as the filing of this Complaint, and Defendants have performed and continued to perform these acts with knowledge of the '899 patent and with the intent, or willful blindness, that the induced acts directly infringe the '899 patent.

33. On information and belief, Defendants also contribute to the infringement of one or more claims of the '899 patent by making, using, selling, offering for sale, and/or importing a

patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use. Defendants have had knowledge and notice of the '899 patent at least as early as the filing of this Complaint, and Defendants have performed and continued to perform these acts with knowledge of the '899 patent and with the intent, or willful blindness, that they contribute to the direct infringement of the '899 patent.

COUNT II: PATENT INFRINGEMENT OF U.S. PATENT NO. 9,095,357

34. On information and belief, the accused products that are made, used, sold, offered for sale, or imported within the United States after importation by Defendants infringe one or more claims of the '357 patent, either literally or under the doctrine of equivalents.

35. A claim chart that applies independent claims 1, 12, and 17 of the '357 patent to a representative accused product is attached to this Complaint as Exhibit 4.

36. On information and belief, Defendants directly infringe one or more claims of the '357 patent through their manufacture, use, sale, offer for sale, and importation of one or more accused products, in the United States.

37. On information and belief, Defendants knowingly and intentionally induce users of one or more of the accused products to directly infringe one or more claims of the '357 patent by encouraging, instructing, and aiding one or more persons in the United States, including but not limited to end users who test and operate accused products at the direction of Defendants, to make, use (including testing those devices and methods), sell, offer to sell, or import one or more of the accused products in the United States, in a manner that infringes the '357 patent.

Defendants have had knowledge and notice of the '357 patent at least as early as the filing of this

Complaint, and Defendants have performed and continued to perform these acts with knowledge of the '357 patent and with the intent, or willful blindness, that the induced acts directly infringe the '357 patent.

38. On information and belief, Defendants also contribute to the infringement of one or more claims of the '357 patent by making, using, selling, offering for sale, and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use. Defendants have had knowledge and notice of the '357 patent at least as early as the filing of this Complaint, and Defendants have performed and continued to perform these acts with knowledge of the '357 patent and with the intent, or willful blindness, that they contribute to the direct infringement of the '357 patent.

JURY DEMAND

39. Pursuant to Federal Rules of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request that the Court enter judgment in Plaintiffs' favor against Defendants, and provide Plaintiffs the following relief:

A. a finding that Defendants have infringed one or more claims of the Patents in-Suit under 35 U.S.C. § 271(a), (b), and/or (c) and a final judgment incorporating the same;

B. a finding that Defendants' continued infringement of the Patents-in-Suit has been and is willful and/or an order increasing damages under 35 U.S.C. § 284;

C. equitable relief under 35 U.S.C. § 283, including, but not limited to, an injunction that enjoins Defendants and any of their officers, agents, employees, assigns, representatives,

privies, successors, and those acting in concert or participation with them from infringing, contributing to, and/or inducing infringement of the Patents-in-Suit;

D. an award of damages sufficient to compensate Plaintiffs for infringement of the Patents-in-Suit by Defendants through the date of judgment, including Plaintiffs' lost profits, together with prejudgment interest under 35 U.S.C. § 284;

E. entry of an order compelling Defendants to compensate Plaintiffs for any ongoing and/or future infringement of the Patents-in-Suit, in an amount and under terms appropriate under the circumstances, and payment of any supplemental damages as appropriate and post-judgment interest after the date of judgment under 35 U.S.C. § 284;

F. a judgment holding that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs reasonable attorney fees, costs, and expenses;

G. an accounting of Defendants' infringing activities through trial and judgment; and

H. such other relief that the Court deems just and proper.

Dated: April 9, 2018

Respectfully submitted,

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